Dicamba

October 15, 2019

Briefing Outline

- EPA Decisions and Context
- Technology Adoption and Incidents
- Current Work and Next Steps

Timeline

- 2015 – Seed deregulation by USDA
- 2016 Season – Incidents due to misuse
- Fall 2016 – First "over-the-top" (OTT) products registered
- 2017 Season – Substantial adoption and incident reports
- Fall 2017 – Label changes for 2018 season
- 2018 Season – Increasing adoption and ongoing incidents
- Fall 2018 – Completed new assessments and extended registration for 2 more years with additional label changes
- 2019 Season – Very high technology adoption in soybeans; reports of drift incidents continue

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What is dicamba?

- A synthetic auxin herbicide first registered in the US in 1967
- Widely used on agricultural crops, fallow land, pastures, turfgrass and rangeland
- Also registered for non-agricultural uses in residential areas and other sites, such as golf courses.
  - On non-ag. Sites, used primarily to control broadleaf weeds such as dandelions, chickweed, clover and ground ivy

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What is dicamba?

- Historically, most agricultural dicamba applications occurred late winter or early spring
  - Broadleaf weed control prior to planting crops
- Registered for use in agriculture on corn, wheat, cotton, soybeans and other crops.
- Many plant species (including 100+ crop species) are sensitive to dicamba (can be damaged) and off-site movement has been a long-standing issue

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Federal Oversight of Herbicide Tolerant Crops

- Both USDA and EPA have roles
  - USDA evaluates transgenic crops including herbicide tolerant seeds
  - EPA makes registration decision for the use of a pesticide on an herbicide tolerant crop
- It's helpful for USDA and EPA to coordinate and have similar decision timing
  - Area for improvement

Seed Deregulation - 2015

- In January 2015, USDA deregulated Monsanto's cotton and soybeans that are genetically modified to be tolerant to dicamba
- No over-the-top products were registered for use on these dicamba-tolerant (DT) crops at the time

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Impacts of Seed Deregulation Prior to Herbicide Registration – 2016 Season

- As of August 2016 Missouri Department of Agriculture had received approximately 117 complaints alleging misuse of dicamba products, estimated that more than 42,000 acres of crops had been adversely affected
- Damage on peaches, tomatoes, cantaloupes, watermelons, rice, cotton, peas, peanuts, alfalfa, and soybeans
- Similar misuse complaints received by Alabama, Arkansas, Illinois, Kentucky, Minnesota, Mississippi, North Carolina, Tennessee and Texas

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Dicamba Over-the-Top Uses vs. Historical Uses of Dicamba

- First dicamba applications for over-the-top (OTT) of DT soybeans and cotton
- Timing of applications - Applied later in the year, when other plants and crops would be more sensitive.
- Rates
  - Double single app. rate to DT cotton vs. non-DT
  - Double total per year to DT soybeans vs. non-DT

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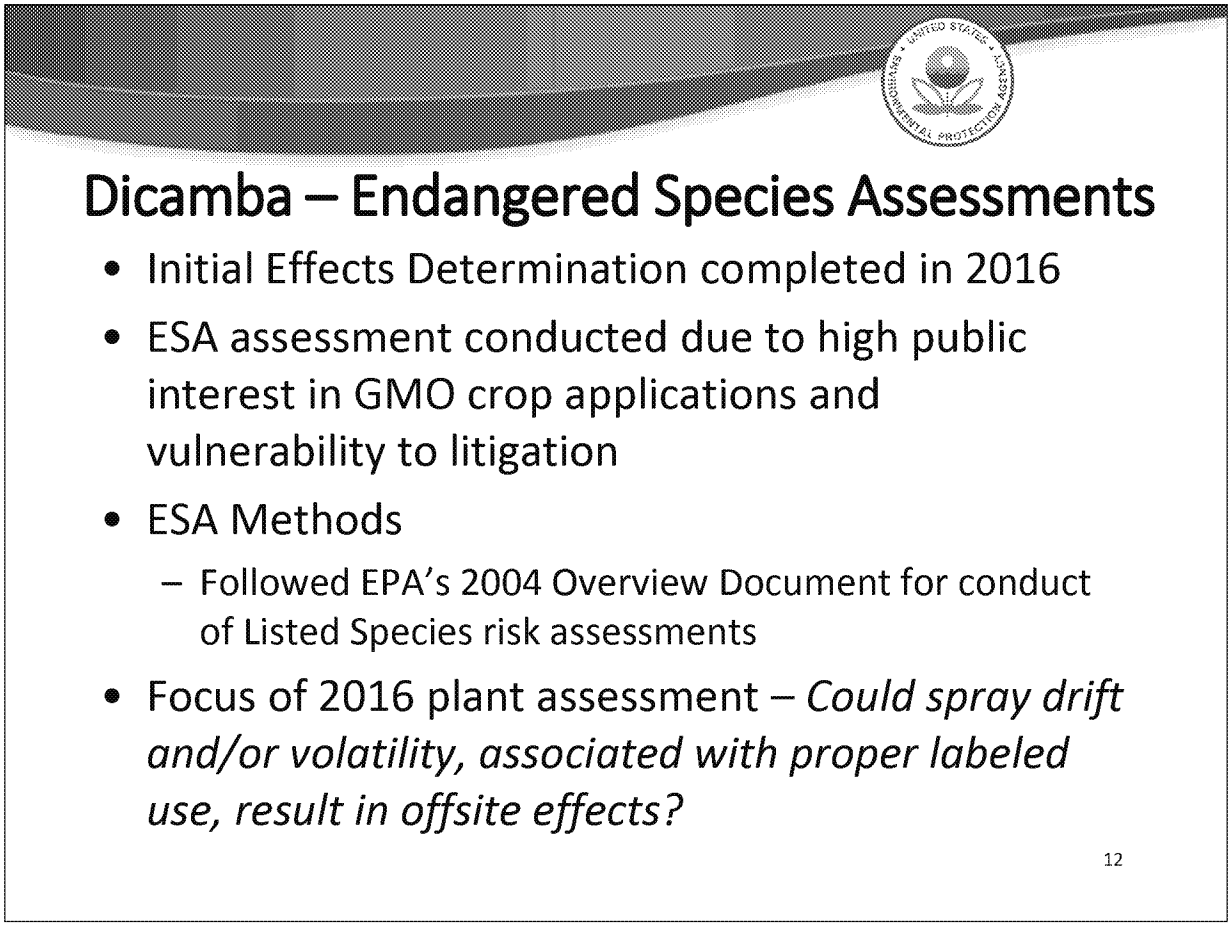
Dicamba Over-the-Top Uses – Human Health Risk Assessment

- There are no dietary risks of concern even when high-end residue assumptions are used
- No risks of concern for occupational handlers or post-application workers
- There are no risks of concern for people applying dicamba to home lawns or to adults or children playing on those lawns
- There are no risks of concern for bystanders exposed near agricultural fields resulting from volatility of dicamba, even at the edge of the field

RD (for HED)



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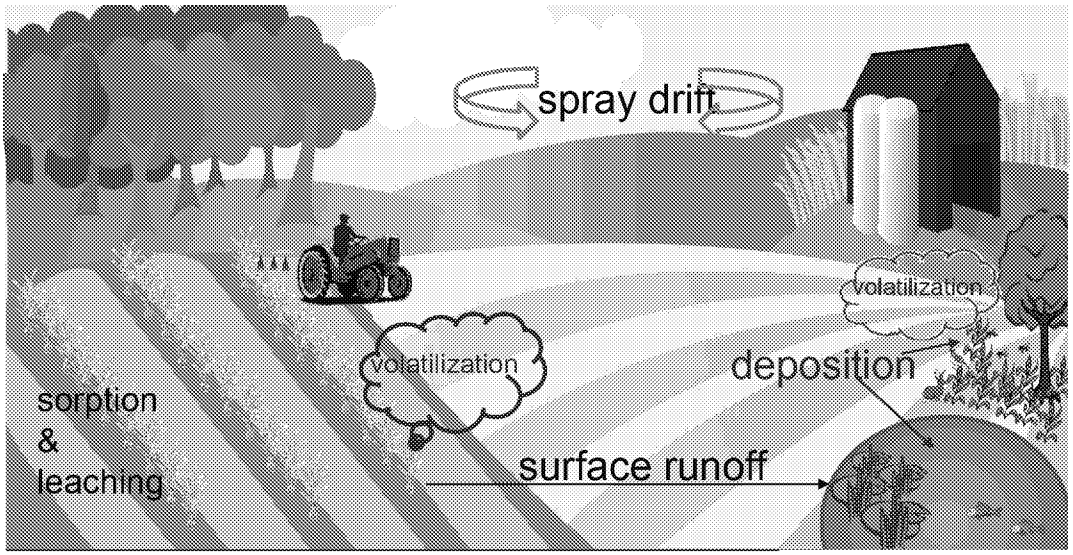
Did not use 2016 "interim ESA methods", as they were designed for use in ESA Biological Evaluations (BE) of specific pilot chemicals for registration review. This was consistent with the strategy that we laid out in our report to Congress.

Spray Drift vs Volatility



Spray drift is the movement of droplets through the air to any off-target site during, or shortly after, application

Volatility is a tendency of a substance to vaporize (i.e., go from a liquid to a gas) or the speed at which it vaporizes

Dicamba – Endangered Species Assessments

- Conclusions of 2016 Effects
  - Spray drift
    - Weight-of-evidence approach using modeling and field data
    - A 110-foot infield, wind-directional buffer adequate to protect endangered species and was included on the label
  - Field volatility data
    - Registrant studies in GA and TX and modeling for areas in the mid-West (i.e., MO and IN) indicated air concentrations at the edge of the field were below plant effects levels
    - Conclusion: off-field volatility was not an issue and that no buffer was needed to protect species from volatility

Dicamba Over-the-Top Uses Benefits Assessment

- Additional mode of action herbicide for difficult to control broadleaf weeds during the crop growing season.

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Risk Management Challenges

- Dicamba is known to move off-site through many transport mechanisms
  - Volatility
  - Drift and wind movement
  - Temperature inversions
  - Tank contamination
- Pronounced damage can occur to sensitive crops from very low levels of exposure to dicamba
- Weed resistance
- Endangered Species Act

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Dicamba Over-the-Top Uses – 2016 Decision

- New uses for dicamba-tolerant (DT) soybean and DT cotton were registered in late 2016 in 34 states
- Only dicamba products specifically registered for use on DT cotton and soybeans can legally be applied OTT
- Three products were approved for use with 2-year expiration dates
  - Xtendimax with VaporGrip Technology (Monsanto/Bayer)
  - Engenia Herbicide (BASF)
  - DuPont FeXapan Herbicide Plus VaporGrip Technology (DuPont/Corteva)

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Dicamba Over-the-Top Uses
2016 Decision - Why expiration dates?

- Expiration dates would ensure that the EPA retains the ability to easily modify the registration or allow the registration to terminate if necessary
  - 2 Years - Off-site incidents potentially due to the illegal use of dicamba products occurring at unacceptable levels
  - 5 Years – Cases of dicamba resistant weeds occuring at unacceptable levels. (With the development of dicamba resistant weeds, the benefits of OTT dicamba would be greatly reduced.)

Ex. 5 Deliberative Process (DP)

2016 Over-the-Top Uses Labeling

- The three products had close to identical labeling and restrictions
- No application from aircraft
- No application when wind speed is over 15 mph
- Application only with approved nozzles at specified pressures
- Required buffer zones to protect sensitive areas when the wind is blowing toward them

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Additional Unique Terms of Registration for OTT Dicamba 2016 Decision

- Maintain website listing approved tank mixes
- Herbicide Resistance Management Plan
  - Field detection and remediation
  - Education
  - Evaluation
  - Best Management Practices from WSSA
  - Reporting of "likely resistance"

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2017 Season - Dicamba Incidents

- First year of legal use
- May/June 2017 EPA started receiving reports of significant crop damage resulting from off-field movement of dicamba
- Early cases were reported in Bootheel of Missouri
- As the season progressed, reports of soybean damage spread across southern states and northern MO, into the Midwest and Dakotas

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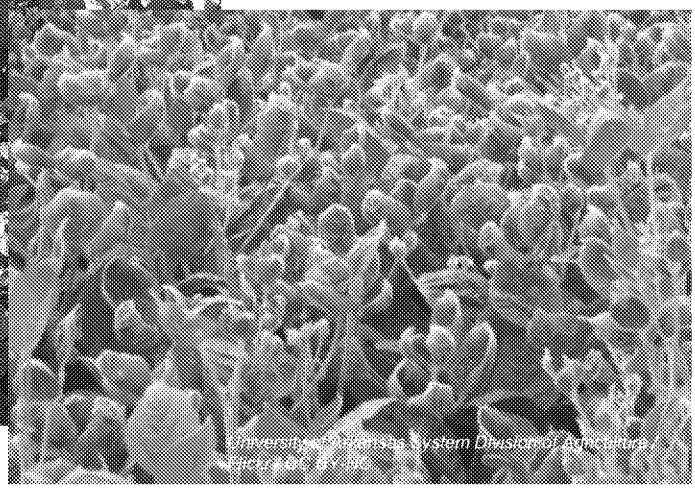
DT - soybeans

Non-DT - soybeans



Dicamba Damaged Soybeans

Dicamba Damaged Sumac

William Jacobi, Colorado State University, Bugwood.org


Non-DT
(Enlist)
DT

2017 Season - Dicamba Incidents

- States developed 24(c) labels with specific restrictions for their state only to combat off-site movement
  - Alabama, Georgia, Louisiana, North Carolina, New York, Missouri, Arkansas, Mississippi, Indiana, South Dakota, Florida
  - Required specific enhanced training, windspeed restrictions, time of application restriction, Restricted Use Pesticide – application by certified applicators only
- Typically states desire to make Federal label less restrictive through 24(c) process
- Missouri issued a Stop Sale, Use or Removal Order (SSURO) July 7, 2017 – halted all sales and use of dicamba pesticides for agricultural uses until 24(c) was registered

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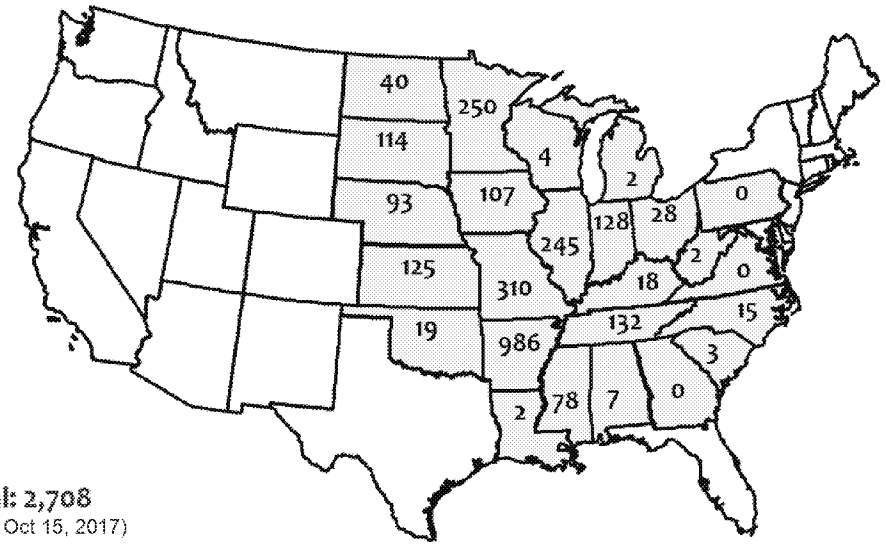
2017 Season - Dicamba Incidents

- 2,708 official dicamba-related crop injury investigations as of October 15, 2017 (collected by Univ. of Missouri Ag. Extension as reported by state departments of agriculture)
- More than 3.6 million acres of soybeans impacted
- Other impacted crops: tomatoes, watermelon, cantaloupe, vineyards, pumpkins, vegetables, tobacco, residential gardens, trees and shrubs

Characterization of 2017 Season Incident Data

- Companies potentially reporting much lower numbers than others
- Growers can be reluctant to report their neighbors
- Potentially difficult for states to verify reported incidents
- Not all reports of crop damage were reported to State Departments of Agriculture (1 in 5 cases?)

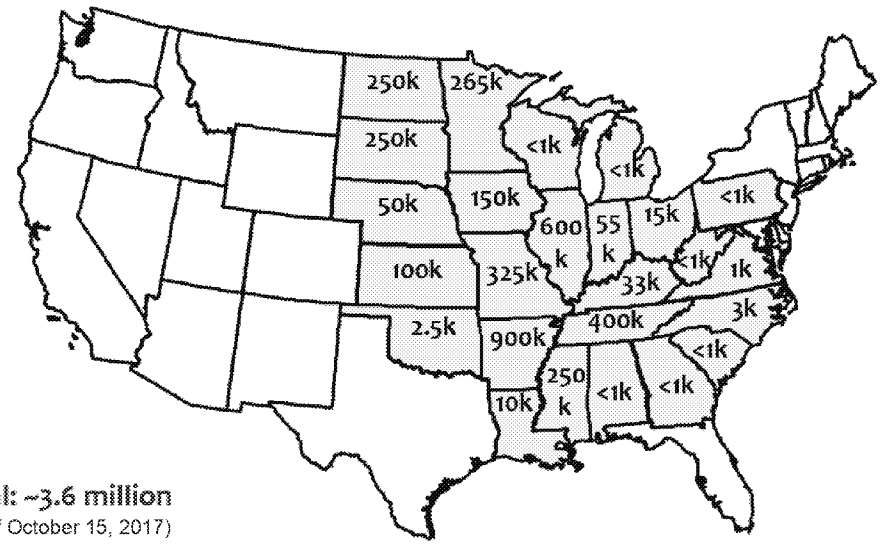
Dicamba-Related Injury Investigations Reported by State Departments of Agriculture



***Total: 2,708**
(*as of Oct 15, 2017)

Source: *Univ. of Missouri, IPM, Dr. Kevin Bradley*
https://ipm.missouri.edu/IPCM/2017/10/final_report_dicamba_injured_soybean/

Estimated Dicamba-Injured Soybean Acreage



*Total: ~3.6 million
(*as of October 15, 2017)

Source: Univ. of Missouri, IPM, Dr. Kevin Bradley
https://ipm.missouri.edu/IPCM/2017/10/final_report_dicamba_injured_soybean/

Impacts to State Agencies – 2017 Season

- Significant amount of time went to investigations in 2017
- Result = other programs suffered
- No additional personnel or funding

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Summary of Investigations – EPA's Response to 2017 Incidents

- EPA engaged State Lead Agencies and University Weed Scientists soliciting information to cooperatively develop solutions to remedy the unacceptable dicamba incidents reported in the field
- Cooperative efforts among University Academic, Industry, and Growers were used to inform EPA's regulatory decision making

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Summary of 2017 Season Investigations

Possible routes/causes of off-site movement of dicamba:

- Physical Drift
- Tank Contamination
- Temperature Inversion
- Volatility
- Misuse
  - Other dicamba products, though illegal to use OTT, are much cheaper and readily available
  - Impossible to tell which dicamba product caused damage
  - OTT Label is complex and difficult to follow
  - Registrants claimed this was main cause

Purdue University Weather Data for June 2017
Only 49 hours in June when applications could be made
Followed Missouri Emergency Rules
Applications only between 9 am and 3 pm and maximum wind speed of 10 mph

Label Changes for 2018 Season

- In response to the 2017 season incidents, EPA negotiated label changes with the registrants
- Completed changes in late 2017, so products could be relabeled before the 2018 season
- EPA's goal: minimize off-target movement and reduce incidents for 2018 growing season
  - Further minimize the potential for off-target movement by addressing application practices
  - Reduce ambiguity in application directions across registered products
  - Retain the utility of the technology recognizing the benefit as an important tool for managing weed resistance

Label Changes for 2018 Season

- Products are now Restricted Use Pesticide (RUP) products
  - For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification
- Dicamba-specific training is required for all applicators
- Each label limits applications to when maximum wind speeds are below 10 mph (from 15 mph) to reduce potential spray drift
- Applications may only occur between Sunrise and Sunset
- Tank clean-out language to prevent cross-contamination
- Susceptible/sensitive crop identification and record keeping with sensitive crop registries to increase awareness of risk to especially sensitive crops near application site
- RUP designation requires applicators to maintain specific records regarding the use of these products

All registrants agreed to a process to get the revised labels into the hands of farmers in time for the 2018 use season
Reports estimated nearly 95,000 applicators were trained ahead of the 2018 season

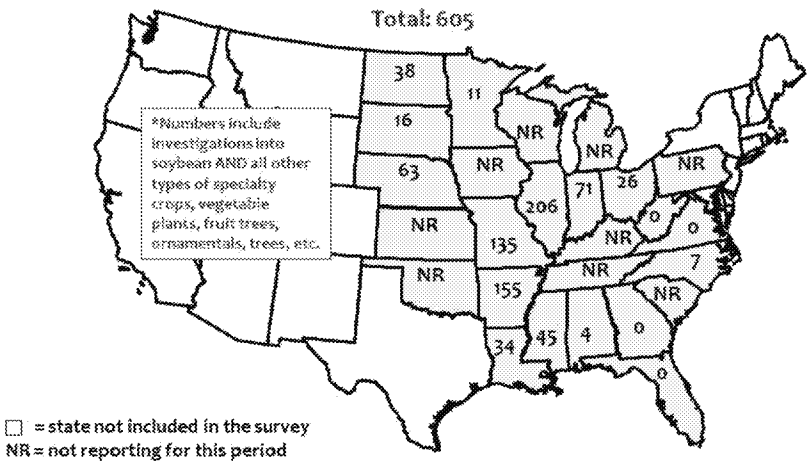
State 24(c) Labels for 2018 Season

- Certain states again decided to impose additional restrictions to the Federal labels
- MO, GA, AL, NC, LA, NY, TN, AR, IN, IA, ND
  - These states produce 41% of US soybeans
- Restricted hours of application, cutoff dates, specific additional training requirements, altered record keeping requirements, hooded sprayer requirements, temperature restrictions, certified applicators only, tractor speed restrictions

2018 Season Incidents

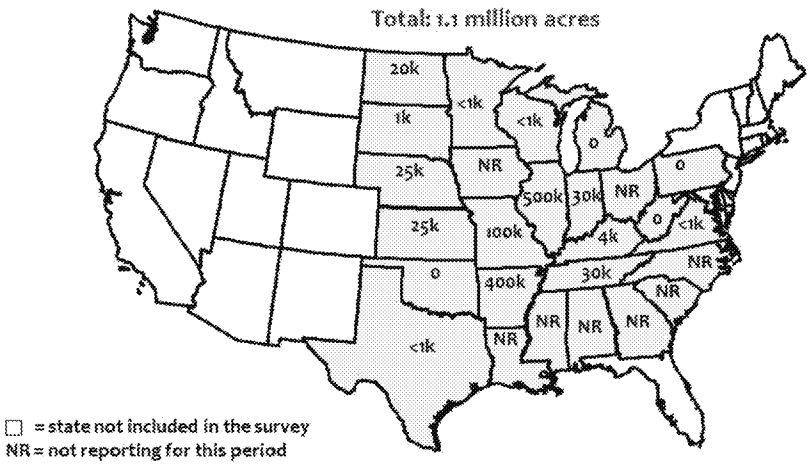
- As of June 1st, most documented dicamba injury occurred to specialty crops, vegetables, and ornamental, fruit, and shade trees
- As of July 15th, 1.1 million acres of soybean damage reported
- State leads suggest major under-reporting of damage
- Much higher adoption of DT soybeans than previous years

Official Dicamba-related Injury Investigations as Reported by State Departments of Agriculture (as of July 15, 2018)



*Dr. Kevin Bradley, University of Missouri

Estimates of Dicamba-injured Soybean Acreage in the U.S. as Reported by University Weed Scientists (as of July 15, 2018)



*Dr. Kevin Bradley, University of Missouri

Impacts to State Agencies – 2018 Season

- Injury investigations continue to cause significant strain on these agencies in 2018
  - Dealt with 2 to 3 times the number of investigations
  - Other programs suffered
  - No additional personnel or funding

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2018 Actions

Ex. 5 Deliberative Process (DP)

- ESA Re-evaluation

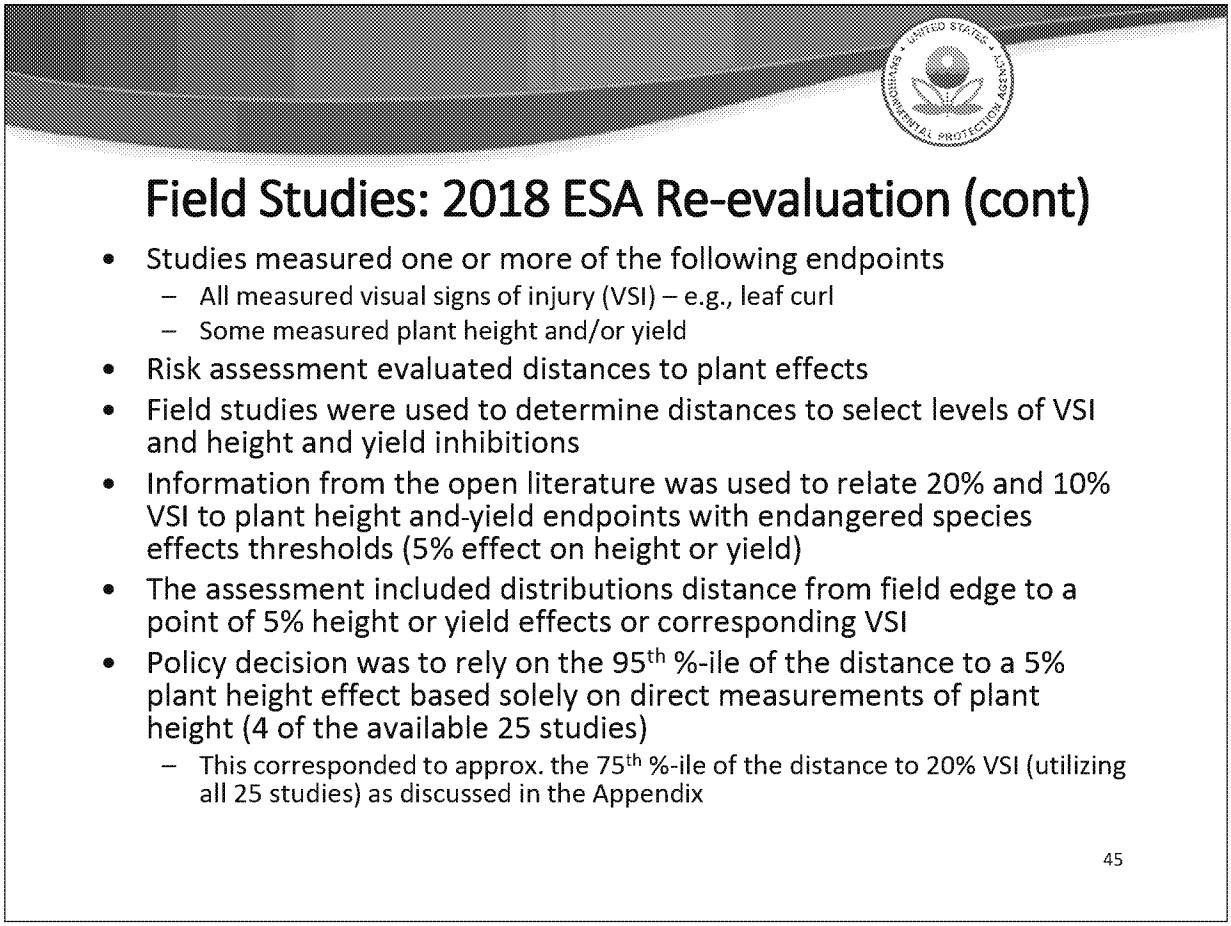
Dicamba – Endangered Species Assessments

- 2018 ESA Re-evaluation was also a plant focused risk assessment
  - No new information to alter risk profile for non-plant species
- Focus of 2018 plant assessment - *Were off-site incidents associated with drift and proper labeled use?*
  - Incident information (e.g., incident counts and acres of soybean damage reported to states) indicated potential discrepancies between previous risk assessments and conditions alleged in the field
  - Field studies were used to evaluate:
    - Was spray drift occurring beyond estimated buffer, resulting in offsite plant damage?
    - Was volatility occuring and resulting in offsite plant damage?
    - Was there a combined effect, from spray drift and volatility, that was not being addressed in the previous risk assessment?

Field Studies: 2018 ESA Re-evaluation

- Relied upon field data which provided data on distances to relevant plant damage
- Field data consisted of mixture of effects data (i.e., plant damage) and measurements (i.e., concentrations) to quantify potential exposure and effects off the treated field (studies completed in 2017 and 2018)
  - Registrant submitted - 8 field studies. Sites covered: Georgia(2), Texas (4), Australia (1), Arizona (1)
  - Academic submitted - 9 field studies. Sites covered: Arkansas (3), Indiana (4), Nebraska (3), Tennessee (2), Missouri (2), Wisconsin (1), Michigan (1)
  - Open literature study (Jones, AR, May 2018) – included eight transects with differing levels of damage
  - Open Literature studies relating visual signs of damage in the field to effects on height and yield
- Field studies evaluated effects to soybeans, the most sensitive tested plant species, which is used as a surrogate for all other plants, including listed species

Ex. 5 Deliberative Process (DP)



EFED
Because the distance to a 5% effect varied among available field studies and across transects within those studies, EFED created a distribution of the distances to 5% effect and then provided policy makers with the percentiles from that distribution so policy makers could set appropriate buffers that would consider the whole distribution and reflect their need for a degree of certainty of protection.

Conclusions of 2018 ESA Re-evaluation

- How were these results incorporated into the labels?
  - Buffers to address off-field ESA protected species
    - 57-foot infield omnidirectional buffer (volatility)
    - 110-foot infield wind-directional specific buffer (spray drift)
  - On-field species addressed by off-labeling counties where they occur (e.g. Wilson County, TN)
  - ESA restrictions implemented using Bulletins Live Two (BLT)
- Additional data requirements – Conditions of Registration
    - Field studies evaluating off-target movement and plant effects in areas of highest incidents (IL, MO, MS)
    - Irrigation study to evaluate the levels of dicamba in irrigation water following treatment
    - Yield studies paired with off-field movement studies, designed to evaluate distance to effects on reproduction
    - Toxicity studies evaluating effects to woody plant species
    - Laboratory studies evaluating the impacts of pH and temperature on volatility

Ex. 5 Deliberative Process (DP)

Dicamba Over-the-Top Uses Benefits Assessment – 2018 Decision

- Additional postemergence herbicide for difficult to control broadleaf weeds during the crop growing season.
- May delay evolution of herbicide resistance when used as part of a season-long weed management program that includes multiple-effective modes-of-action and preemergence (residual) and postemergence (foliar) herbicides.

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Informing the 2018 Regulatory Decision

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2018 Registration Decision for 2019-2020 Seasons

- EPA decided to continue the registration for another 2 years, to expire December 2020
- Conditions of Registration
  - Additional Data Requirements
  - Enhanced Reporting
    - 6(a)2
    - Herbicide resistance
    - Dicamba residues
    - Study summaries

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Label Changes for 2019-2020 Season

- Only certified applicators may apply dicamba over the top. (Those working under the supervision of a certified applicator may no longer make applications.)
- Over-the-top application of dicamba on soybeans 45 days after planting and cotton 60 days after planting is prohibited.
- For cotton, the number of OTT applications allowed was reduced from four to two (soybeans remain at two OTT applications).
- Application is allowed only from one hour after sunrise to two hours before sunset.

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Label Changes for 2019-2020 Season

- In counties where endangered species may exist, the downwind buffer will remain at 110 feet and there will be a new 57-foot buffer around the other sides of the field. The 110-foot downwind buffer applies to all applications, not just in counties where endangered species may exist.
- The training period is clarified to require annual applicator certification for 2019 and beyond, ensuring consistency across all three products.
- Improved tank clean-out instructions for the entire system.
- Enhanced to improve applicator awareness of the impact of low pH on the potential volatility of dicamba.
- Labels have been cleaned up and made more consistent to improve compliance and enforceability.

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New Product – Tavium (Syngenta)

- EPA registered an additional product for use OTT of DT cotton and soybean in Early 2019
- Contains a combination of dicamba and s-metolachlor
  - This combination of active ingredients is currently an approved tank mix, so was already used over the top on cotton and soybeans.
- Same label restrictions, training needs, data requirements, and other conditions as the currently registered dicamba products
- Same conditions of registration as the original 3 OTT products

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2019 Season State 24(c) Labels

- Certain states again decided to impose additional restrictions to the Federal labels
- Specific training requirements, cutoff dates, etc.
- NC, IA, SD, MN, ND, IL, GA, AL, TX, LA
- IL amended, extending cutoff date due to late plantings

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2019 Season Incidents

- Incidents were later in the year due to unique weather
- Incident numbers are being collected
- Preliminary reports suggest incidents vary state to state
  - The two states with increasing complaints seem to be Indiana and Illinois
  - Incidents involving soybean have gone down in other states (NE, MO)
    - Increased plantings of DT-soy (NE,TN)
- Incidents involving other sensitive vegetation (e.g., trees and gardens) expected to remain constant or increase

Impacts to State Agencies - 2019

- Impacts may vary state to state
  - Increased incidents = burden to state
    - Some states have streamed-line investigations to adjust to the new normal (e.g., Indiana)
  - Fewer incidents = reduced impacts on the state

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Incidents - Sociological Impacts

- Freedom to farm (chemical trespass)
- Reluctance to report misuse and incidents
- Intimidation
- Damage from off-site movement used as part of DT seed sales pitch
- Agricultural communities are being divided

Ex. 5 Deliberative Process (DP)


REWARD OFFERED
FOR ANY INFORMATION ABOUT WHO IS
REPORTING OUR LOCAL FARMERS TO THE
ARKANSAS STATE PLANT BOARD FOR DICAMBA
USE. IF YOU HAVE ANY INFORMATION, PLEASE
CALL THE NAME AND NUMBER BELOW.
MR. SOMETHING
870-816-5994

Dicamba Over-the-Top Uses Performance – 2019 Season

- Reports of dicamba non-performance (possible resistance) increasing.
  - TN, IL, IN
  - Confirmation of resistance in progress (can take months to years).
- Antagonism between glyphosate and dicamba causing reduction in grass control.
- Overall benefits decline as resistance increases or antagonism occurs.
- 2018 benefits assessment did not consider impacts of off-site movement.

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Palmer amaranth escapes

Goosegrass escapes

59

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2019 Interactions with State Agencies

- Pace of direct state feedback slowed down over the 2019 season
- Recently, certain state representatives are beginning to reach out, so cooperative efforts are planned for late 2019 with State Lead Agencies and University Weed Scientists
  - OPP soliciting information to cooperatively develop solutions to remedy the unacceptable dicamba incidents reported in the field

Studies Required as Condition of 2018 -2020 Registration

Ex. 5 Deliberative Process (DP)

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Pending Dicamba Actions

Ex. 5 Deliberative Process (DP)

Next Steps

Ex. 5 Deliberative Process (DP)

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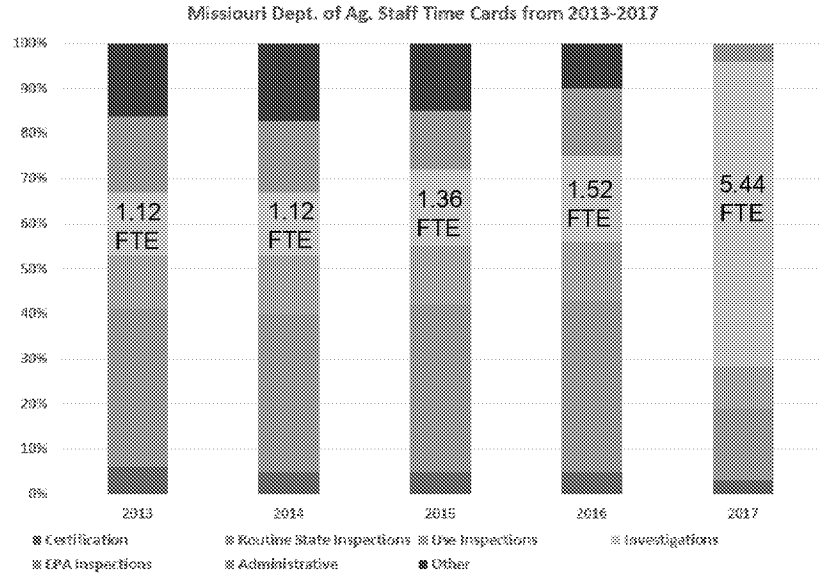
Litigation

- Legal challenge to Bayer's Xtendimax 2018 Registration (*Dicamba II*)
  - *National Family Farm Coalition v. EPA* (9th Cir. No 19-70115)
- Brief to be filed October 15, 2019
- No date scheduled for oral argument (likely late winter/early spring 2020)

Questions?

Back Pocket Information

Impacts on State Regulatory Agencies



Source: Dawn Wall, Pesticide Program Administrator, MoDA, Email to Shawn Hackett, EPA Region 7, dated July 16, 2018

Ex. 5 Deliberative Process (DP)

Estimated Planting and Harvest Dates for Soybeans and Other Sensitive Crops in Illinois, Estimated Application Window for Preplant and OTT Dicamba Applications, and Comparison of Reported Dicamba-related Incidents[1] in 2017 and 2018

	Mar	April	May	Jun	Jul	Aug	Sep	Oct
Preplant Burndown Dicamba Application (all formulations)								
Soybean Planting Window								
OTT Application Window								
Reported Incidents Window (2017)								
Reported Incidents Window (2018)								
	Planting to Harvest Window for Sensitive Crops							
Non-dicamba Tolerant Soybean								
Lima Beans								
Snap Bean								
Cabbage								
Green Peas								
Pumpkin								

[1]Majority of incidents in Illinois were to non-dicamba tolerant soybean.
Sources: USDA 2018b (5-yr average); AAPCO, 2018; USDA, 2010; USDA, 2007.